

Original article:

Effectiveness of Topical Acetic and Gentamicin in Patients of Chronic Suppurative Otitis Media Using Otological Symptoms Score in a Tertiary Care Teaching Hospital

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Abstract

Introduction: Chronic Suppurative Otitis Media (CSOM) one of the sicknesses impervious to current anti-toxins; holding on for over two week; and fit for bringing about extreme release, tympanic layer aperture and deafness. This may bring about misery and influence their personal satisfaction and profitability.

Methods: It was a Randomized, open label study conducted on 150 patients. Patients diagnosed as CSOM (safe type) were randomly divided into two groups, group I - topical 1.5% Acetic acid and group II - topical 0.3% Gentamicin sulphate in a dose of three otic drops thrice daily. Follow up was done every week for two weeks and was compared on the basis of otological symptoms score.

Results: The mean difference of otological symptom score at day 7 and day 14 from baseline in Group I was 1.80 ± 1.01 and 3.22 ± 1.08 ; and in Group II 1.86 ± 0.54 and 3.44 ± 0.74 ; $p < 0.05$. Among the study groups, reduction of otological symptom scores at day 7 (Group I = 3.12 ± 1 , Group II = 2.86 ± 1.36 ; $p = 0.14$) and at day 14 (Group I = 1.62 ± 1.36 , Group II = 1.60 ± 1.54 ; $p = 0.56$) respectively. Also, "Treatment success" seen in 92% patients in the Acetic acid group and 84% patients in Gentamicin sulphate group.

Conclusion: Topical Acetic acid and Gentamicin sulphate found to be equally effective for the treatment of CSOM.

Keywords: Chronic Suppurative Otitis Media, Gentamicin, Acetic Acid

INTRODUCTION

As indicated by World Health Organization (WHO), Chronic Suppurative Otitis Media (CSOM) is characterized as an incendiary state of the ear that causes repetitive ear release (otorrhoea) through puncturing of the ear drum (tympanic layer).¹ The sickness more often than not starts in youth, bringing about unconstrained tympanic aperture because of an intense contamination of the center ear, known as intense otitis media (AOM), or as a sequelae of less extreme types of otitis media (otitis media with emission).¹ Later on, if disease persists, it may lead to complications such as, recurrent acute otitis media, persistence of middle ear effusion, hearing impairment, mastoiditis, meningitis, brain abscess and sepsis.²

The clinical appraisal of the exhibiting ear in CSOM requires a cautious assessment of the history and examination, both of which are fundamental in deciding the sort, state and the degree of the malady procedure, preceding the administration system.³ Traditionally CSOM is divided into two types: Tubotympanic (safe) type of CSOM and Atticoantral (unsafe) type of CSOM.⁴ It is well documented that, patients with tubotympanic type of CSOM can be managed with empirical medical therapy to control the infection and eliminate ear discharge.⁵ Among therapeutic treatment, standard aural can; insufflation of topical germ-free, organization of topical and additionally systemic anti-microbials is the pillar of the therapy.^{6,7} Several topical specialists, for example, antibacterial, steroids and corrosive media ear

drops are generally utilized alone or in mix to control the disease.^{6,7}

Various previous studies showed that most common organisms found in CSOM are Staphylococcus aureus, Pseudomonas aeruginosa, Proteus mirabilis, Klebsiella pneumonia, E.coli, Aspergillus species and Candida.^{8,9} Aminoglycosides such as amikacin, gentamicin, tobramycin and fluoroquinolones such as ciprofloxacin are commonly used antibiotics in patients with otitis media.¹⁰ However, due to increased and irrational use of wide-spectrum antibiotics, the resistance in the bacterial isolates has become very common.⁹

Topical antiseptics may be as effective as topical antibiotics in resolving otorrhoea as found in several trial.¹² For Acetic acid, various previous studies showed that it was widely used as an antimicrobial agent in different fields; for killing food-borne pathogenic bacteria, to inhibit Escherichia coli growth, and to treat ear infections.¹²⁻¹⁴ The efficacy of acetic acid is based on their ability to reduce the pH in the ear and restrict the growth of microorganisms.¹⁵ In view of this, we aimed to conduct a study to assess the role of topical Acetic acid in comparison to Gentamicin for the management of CSOM.

METHODS

A Randomized, open label study was carried out in the Department of Otorhinolaryngology, Katihar Medical

College, Bihar, for duration of 1 year (December 2013 - November 2014).

Only those patients diagnosed with tubotympanic (safe) type of CSOM based upon detailed history and otoscopic examination were included in the study. On the basis of inclusion and exclusion criteria, 150 patients were enrolled in our study. The study was approved by the institutional ethics committee and written informed consent was taken from each of the subjects.

Patients were then randomly divided in to two groups, group I (n=75) was given topical 1.5% (n=75) acetic acid and group II was given topical 0.3% Gentamicin sulphate in a dose of three otic drops three times daily. All the cases were followed up weekly for total period of two weeks.

The efficacy of two drugs were compared on the basis of otological symptoms score assessed at base line (day 0), day 7 and on day 14. Number of subjects achieving “treatment success” in each treatment group at the end of the study was considered to be an effective parameter (Table 1). A difference of 10% in clinical cure rates was assumed to be the largest clinically acceptable effect for which equivalence could be accepted (equivalence limit). Data were presented as mean ± standard deviation (SD) using an SPSS version 16.0. Students paired T-test was applied for the comparison of different variables between the groups.

Table 1: Otological symptom score

Signs/ symptoms	Score 0	Score 1	Score 2	Score 3
Tinnitus	Absent	Mild	Moderate	Severe
Amount of discharge	Absent	Mild	Moderate	Severe
Type of discharge	Absent	Mucoid	Mucopurulent	Purulent

Table 2: Intragroup comparison of mean difference of otological symptom score.

Visit	Acetic acid group (n=50) Mean ± SD	Gentamicin sulphate group (n=50) Mean ± SD	p value
Day 0	4.45±1.24	3.42±1.55	0.12
Day 7	3.22±1.91	2.86±1.76	0.14
Day 14	1.72±1.76	1.70±1.79	0.56

* & ** = significant, p<0.05. Clinical cure if score <3, Clinical improvement if score 3-5 and Treatment failure if score >5.

Table 3: Intergroup comparison of ontological symptom score

Visit	Acetic acid group (n=75) Mean ± SD	Gentamicin sulphate group (n=75) Mean ± SD	p value
Day 0	4.45±1.24	4.62±1.55	0.12
Day 7	3.22±1.91	2.66±1.76	0.14
Day 14	1.72±1.76	1.50±1.79	0.56

RESULTS

A total of 150 patients were randomly divided in two groups, group-I (n=75) for Acetic acid and group-II (n=75) for Gentamicin sulphate group. Most of the patients were from age groups 31-39 years (38%) with the age range of 10-60 years. The mean age (±SD) of patients in the Acetic acid group was 34.12±11.39 years and in Gentamicin sulphate groups were 29.08±09.16 years. There was male predominance with male (68%) and female (32%).

The baseline otological symptom score were comparable (Group I=5.12±1.54; Group II=4.62±1.55) and showed no significant difference among the two groups (p=0.12). An intra-group analysis was done, which showed that the mean difference of otological symptom score at day 7 and day 14 from baseline (day 0) in the two study groups were significant (Group I = 1.90±1.01, 3.40±1.08; and Group II= 1.96±0.57 and 3.12±0.74; p<0.05). This suggested that both acetic acid and Gentamicin sulphate are effective in reducing the symptoms of CSOM (Table 2).

There was also no significant difference in reduction of otological symptom scores among the study groups at

day 7 (Group I =3.22±1, Group II=2.66±1.76; p=0.14) and at day 14 (Group I = 1.72±1.76, Group II= 1.50±1.79; p=0.56) respectively. This suggested that both Acetic acid and Gentamicin sulphate are equally effective in the treatment of CSOM (Table 3).

“Treatment success” i.e. either clinical improvement or clinical cure was seen in 92% patients in the Acetic acid group and 84% patients in the Gentamycin sulphate group, whereas “treatment failure” was seen in 8% and 12% patients in the Acetic acid group and Gentamycin group respectively.

DISCUSSION

The present study demonstrated that there is a noteworthy lessening in otological manifestations score with both the topical specialists, Acetic acid and additionally Gentamicin sulfate, Also they were observed to be similarly powerful as there was no huge contrast in diminishment of otological side effect scores among the review bunches following one week of the treatment and continued till the finish of the study. This was supported by a study done by Eason et al (OR = 0.67, 95% CL = 0.2, 2.25); where topical antiseptics were found to be just as effective as topical antibiotics; however,

ofloxacin/ciprofloxacin produced high cure rates.¹¹ It was also like the results obtained by Clinical Practice Guidelines of the Philippine Society of Otolaryngology–Head and Neck Surgery 1997 & 2002; where it was found that there is no significant difference between topical antiseptics and topical antibiotics in persistent activity on otoscopy (13/20 [65%] with topical antiseptics, 15/18 [83%] with topical antibiotics; (OR 0.40, 95% CI 0.10 to 1.66). No significant difference was also found between oral antibiotics and topical antiseptics in the rate of persistent activity on otoscopy (8/13 [62%] with oral antibiotics, 13/20 [65%] with topical antiseptics, 15/18 [83%] with topical antibiotics; OR 0.87, 95% CI 0.21 to 3.61).

In a survey of 2235 otolaryngologists in the early 1990s, 84% reported some or the other benefits using topical agents in CSOM and only 3.4% witnessed irreversible ear damage caused by such agents.¹⁶In the present study, 88% patients showed resolution of CSOM and none of

the patients had any kind of ear damage or toxicity. In the present study 1.5% Acetic acid showed that resolution of CSOM was higher with success rate in 92% patients while failure rate 8%. Also Acetic acid was found to be cost-effective than Gentamicin sulphate.

Keeping in view various clinical aspects, including treatment success rate, symptomatic relief of discharge and congestion, topical Acetic acid was found to be equally effective to Gentamicin sulphate suggesting that it is the best alternative when infection is caused by multiple antibiotic resistant strains and at an affordable cost.

CONCLUSION

Thus, in this study we found that Acetic acid was found to be equally effective to Gentamicin sulphate suggesting that it is the best choice when infection is caused by multiple antibiotic resistant strains and at an affordable cost.

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